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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	017191.0042 (MSA-3453)	7945
7590 Bayer Healthcare LLC 511 Benedict Avenue Tarrytown, NY 10591		08/22/2007	EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/608,400

Applicant(s)

PUGIA ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-16 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-16 and 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/11/2007 has been entered.

***Oath/Declaration***

The declaration under 37 C.F.R. section 1.132 filed 4/12/2007 has been reviewed by the examiner.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 4, 6 and 8 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 4 and 6 of copending Application No. 10/608,671. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 – 9, 11 – 16 and 27 – 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claims 1, 9 and 27, the specification is unclear with respect to the newly amended portion reciting that the array of posts are disposed to provide a lower capillary force in the well relative to the capillary force in the capillary passageway. The specification does not appear to specifically disclose this newly claimed feature pertaining to the capillary forces within the device. The specification does not provide sufficient detail, such as specific well, channel or spacing size dimensions, to provide this feature.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 – 9, 11 – 16 and 27 – 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1 and 3 – 8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

Regarding claim 1, it is unclear as to what structural aspect of how the array of posts are disposed that enables a lower capillary force to be provided in the well relative to the capillary in the capillary passageway. For example, are the posts coated with a specific coating to enable this function? Is it the spacing distance between the posts themselves or the spacing distance between the posts and the sidewalls or surfaces of the interior of the well of the device? This claim feature is considered indefinite in that it is unclear as to what specific structure provides the difference capillary forces as claimed. Is there a specific size dimension that enables this function? In claims drawn to an apparatus statutory class of invention, the structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device (see MPEP § 2172.01). Furthermore, a feature that is taught as critical in the specification should be recited in the claims (see MPEP § 2164.08c).

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2. Claims 9, 11 – 16 and 27 – 32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

Regarding claims 9 and 27, it is unclear as to what structural aspect of how the array of posts are disposed that enables a lower capillary force to be provided in the well relative to the capillary in the capillary passageway. For example, are the posts coated with a specific coating to enable this function? Is it the spacing distance between the posts themselves or the spacing distance between the posts and the sidewalls or surfaces of the interior of the well of the device? This claim feature is considered indefinite in that it is unclear as to what specific structure provides the difference capillary forces as claimed. Is there a specific size dimension that enables this function? A feature that is taught as critical in the specification should be recited in the claims (see MPEP § 2164.08c).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

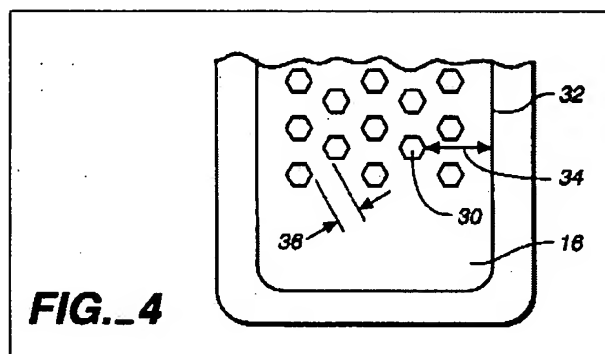
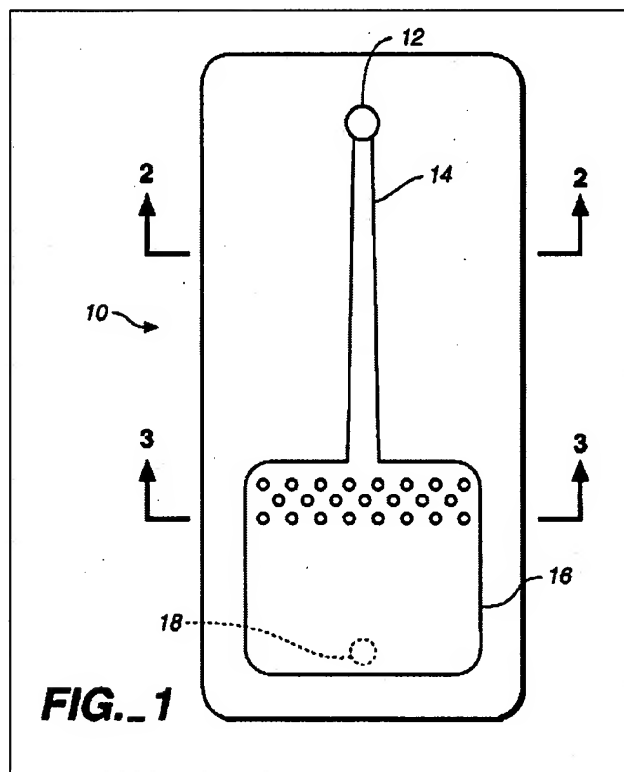
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 9, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler (U.S. Pat. No. 6,113,855 A).

Regarding claims 1, 3, 5 and 6, Buechler anticipates a microfluidic device comprising: an inlet port 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber (e.g., distal region 16) having a substrate surface comprising an array

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of post structures (i.e., capillarity-inducing structures 30) that is also positioned adjacent the substrate; and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4). As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the enclosed inlet chamber 16. Buechler anticipates that the inlet chamber 16 containing the assay volume comprises a reagent (e.g., surface bound reactants comprising solid phase bound antibodies which react with sample antigen) (see, e.g., col. 4, lines 42 – 67; col. 5, line 54 – col. 6, line 5). Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). With respect to the newly added recitation that the array of posts are disposed to provide a lower capillary force in the well relative to the capillary force in the capillary passageway, since the claim does not provide any specific structure or size dimensions for the device, it is unclear as to how this feature defines over the prior art device structure.



Regarding claims 9, 11, 13 and 14, as discussed above, Buechler teaches all of the positively recited structure of the claimed device used to perform the recited method. Buechler anticipates the claimed methodology of distributing a liquid sample uniformly within the disclosed device via capillarity-inducing structures 30 (see, e.g., col. 5, lines 21 – 53; col. 6, lines 23 – 61; col. 8, lines 51 – 65). Regarding process or method claims, a prior art device anticipates



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a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

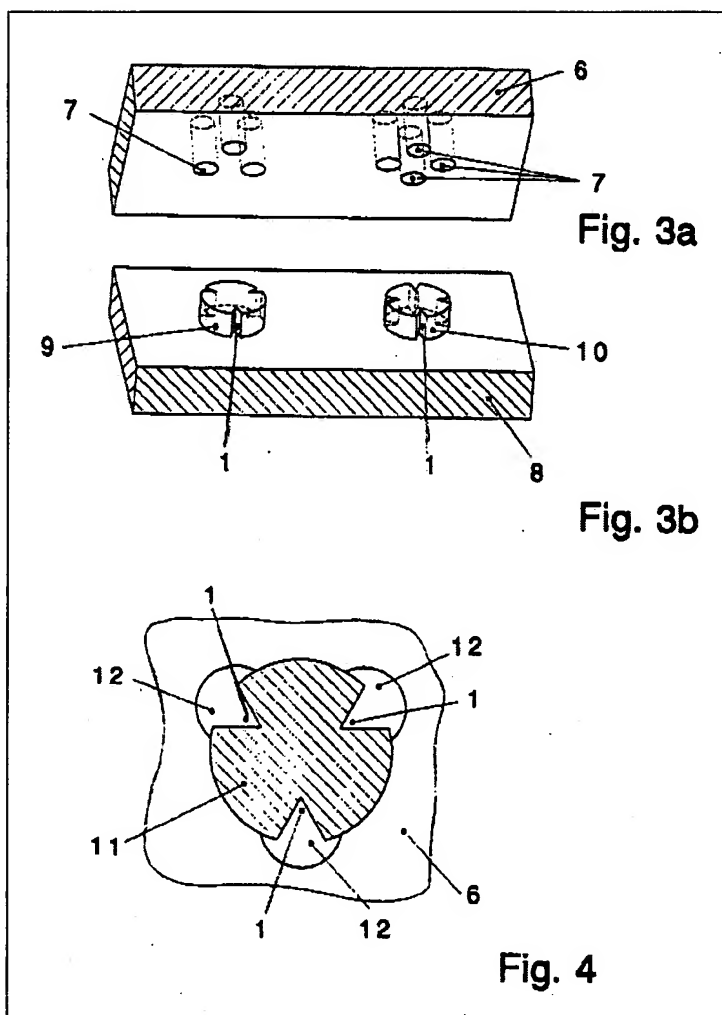
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler in view of Peters (U.S. Pat. No. 6,296,126 B1).

Regarding claims 4 and 12, Buechler is silent to the specific teaching of incorporating wedge-shaped cut-out structures with the disclosed microfluidic device.

As shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).



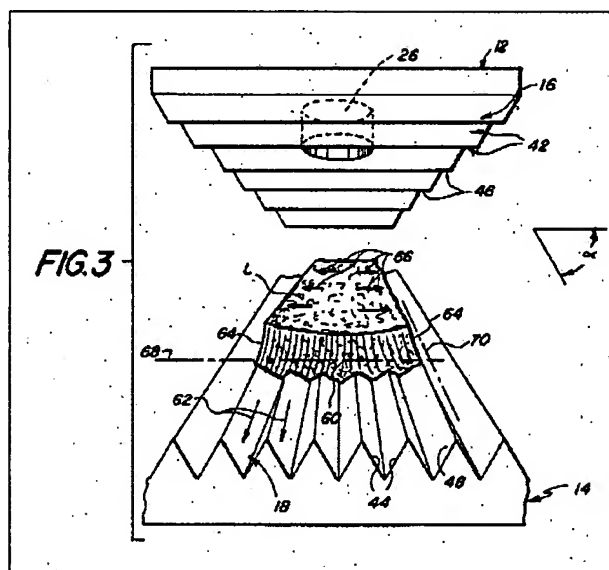
As evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within a microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of

wedge-shaped cut-out structures as claimed with the disclosed microfluidic device in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

2. Claims 7, 8, 15, 16, 27, 28 and 30 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler in view of Columbus (U.S. Pat. No. 4,233,029).

Regarding claims 8 and 16, Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber 16.

Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3).

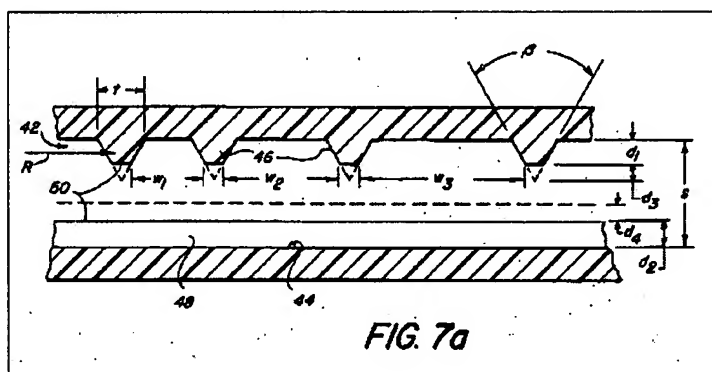


Hence, as shown by Columbus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to

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incorporate a groove structure as claimed with the disclosed microfluidic device in order to facilitate effective uniform sample fluid distribution within the device.

Regarding claims 7 and 15, as shown in figure 7a, Columbus further teaches the incorporation of ramp structures comprising a plateau surface structure configuration (e.g., truncated ridges 46) within the device (see, e.g., col. 8, lines 1 – 51). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a weir structure as claimed for facilitating effective sample fluid flow with the disclosed microfluidic device.



Regarding claims 27, 28 and 30 – 32, Buechler teaches a microfluidic device comprising: an inlet port 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber (e.g., distal region 16) having a substrate surface comprising an array of post structures (i.e., capillarity-inducing structures 30); and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4). As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the enclosed inlet chamber 16. Buechler teaches that the inlet chamber 16 containing the assay volume comprises a reagent (e.g., surface bound reactants comprising solid phase bound

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antibodies which react with sample antigen) (see, e.g., col. 4, lines 42 – 67; col. 5, line 54 – col. 6, line 5).

Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber 16.

Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3). Hence, as shown by Columbus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a groove structure as claimed with the disclosed microfluidic device.

With respect to claim 32, as shown in figure 7a, Columbus further teaches the incorporation of ramp structures comprising a plateau surface structure configuration (e.g., truncated ridges 46) within the device (see, e.g., col. 8, lines 1 – 51). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a weir structure as claimed for facilitating effective sample fluid flow with the disclosed microfluidic device.

As discussed above, Buechler teaches all of the positively recited structure of the claimed device used to perform the recited method. Buechler teaches distribution of a liquid sample uniformly within the disclosed device via capillarity-inducing structures 30. Contiguous with distal region 16 is an escape port or air vent 18 to permit fluids, such as gases, to escape during sample liquid addition, allowing sample fluid flow through the device and into region 16 (see,

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e.g., col. 5, lines 21 – 53; col. 6, lines 23 – 61; col. 8, lines 51 – 65). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method as claimed upon the disclosed microfluidic device to facilitate effective liquid sample distribution within the device and subsequent analysis. It should be noted that the method claims do not recite the use of an applied force to overcome capillary stops, such as via the use of a centrifugal force during use.

3. Claims 9, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler.

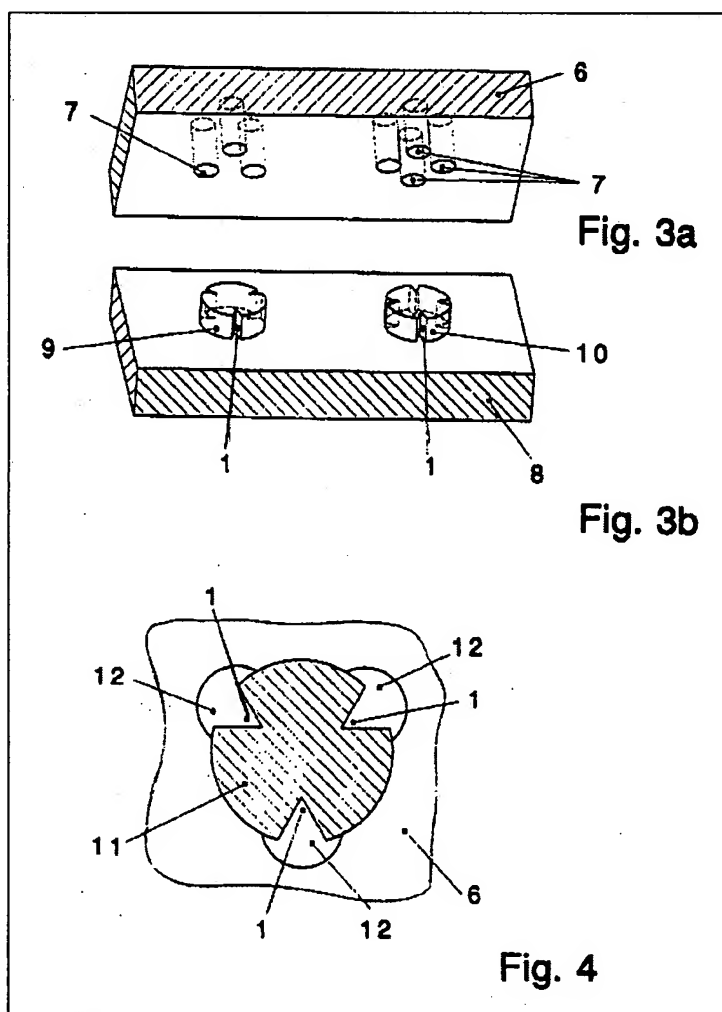
Regarding claims 9, 11, 13 and 14, as discussed above, Buechler teaches all of the positively recited structure of the claimed device used to perform the recited method. Buechler teaches distribution of a liquid sample uniformly within the disclosed device via capillarity-inducing structures 30. Contiguous with distal region 16 is an escape port or air vent 18 to permit fluids, such as gases, to escape during sample liquid addition, allowing sample fluid flow through the device and into region 16 (see, e.g., col. 5, lines 21 – 53; col. 6, lines 23 – 61; col. 8, lines 51 – 65). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method as claimed upon the disclosed microfluidic device to facilitate effective liquid sample distribution within the device and subsequent analysis. It should be noted that the method claims do not recite the use of an applied force to overcome capillary stops, such as via the use of a centrifugal force during use.

4. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler and Columbus, and further in view of Peters (U.S. Pat. No. 6,296,126 B1).

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Regarding claim 29, Buechler and Columbus are silent to the specific teaching of incorporating wedge-shaped cut-out structures with the disclosed microfluidic device.

As shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).



As evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of wedge-shaped cut-out structures within a microfluidic

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apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within a microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of wedge-shaped cut-out structures as claimed with the disclosed microfluidic device in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

### ***Response to Arguments***

Applicant's arguments with respect to amended claims have been considered but are moot in view of the new ground(s) of rejection. In view of the applicants request for continued examination, see the new rejections above and the added remarks.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

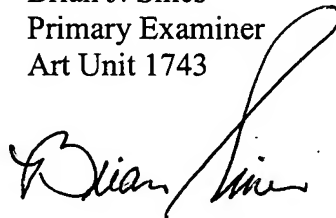
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines  
Primary Examiner  
Art Unit 1743

A handwritten signature in black ink, appearing to read "Brian Sines", with a large, stylized loop at the end of the last name.